**SITE VISIT REPORT FORM**

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| **MCU-FDTMF IRB PROTOCOL CODE** |  | **Date of the Visit**  |  |

|  |  |
| --- | --- |
| **Protocol Title** |  |

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| --- | --- | --- | --- |
| **Name** |  | **Email** | **Mobile / Phone / Fax Number** |
| **Principal Investigator**  |  |  |  |
| **Sponsor** |  |  |  |

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| **Reason for the visit** |  |
| **Person/s interviewed** |  |
| **Total number of expected subjects** |  | **Total subjects enrolled** |  |

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|  | **Yes** | **No** | **Comments** |
| 1. Are site facilities appropriate?
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|  |  |  |  |  |  |
| 1. Is confidentiality of documents maintained (e.g., cabinets with lock and keys)?
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| 1. Are the test articles properly kept and maintained?
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| 1. Are informed Consent Forms completed?
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| 1. Are approved current ICF version used?
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| 1. Are copies of the approved versions of the protocol documents kept in the site?
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| 1. Are files of all communications with the MCU-FDTMF IRB found in the study site?
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| 1. Are copies of adverse event report kept?
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| 1. Are investigator functions properly delegated to qualified research personnel?
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| 1. Is there appropriate documentation of qualifications of personnel?
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| 1. Are all Case Record Forms up to date?
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| 1. Are copies of protocol non-compliance (violation/deviation) reports kept in the study site?
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| 1. Is there evidence of appropriate corrective action taken as recommended by the MCU-FDTMF IRB?
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| **Site Visit Team Conclusions/Recommendations**: |

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| **Duration of Visit (in hours)** |  | **Time Started** |  | **Time Finished** |  |

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| --- | --- | --- |
|  | **Name and Signature** | **Date** |
| **MCU-FDTMF Site Visit Team****Members/Secretariat Staff** |  |  |
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|  |
| **Report prepared by** |  |  |
| **Noted by:****Site Visit Team Leader** |  |  |

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| **MCU-FDTMF IRB Decision** |  |  |  |  |
|  |  |  | No further action |
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|  |  |  | Request additional information, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |
|  |  |  | Recommend further action, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |

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| **MCU-FDTMF IRB Chair** | **Signature** | **Date** |
|  |  |  |